



JUN 23 2003

K030935

IV. Summary of Safety and Effectiveness

**510(k) Summary
for
Berkeley® VC-10 Vacuum Curettage System**

- A. Sponsor** ACMI CORPORATION
136 Turnpike Rd
Southborough, MA 01772
- B. Device Name** Berkeley® VC-10 Vacuum Curettage System
- C. Predicate Device(s)** Berkeley® VC-2 Vacuum Curettage System (Preamendment)
Synevac ®Vacuum Curettage System 10 (K813282)
- D. Device Description**
 - 1. Intended Use**
For rapid transcervical aspiration of the uterine cavity.
 - 2. Technological Characteristics and Substantial Equivalence**

The Berkeley® VC-10 Vacuum Curettage System and Accessories has been tested and compared to similar devices, and is substantially equivalent to the predicates in characteristics described and the parameters tested.
 - 3. Performance Testing**

The Berkeley® VC-10 Vacuum Unit was tested to determine vacuum performance. Sterilization validation was performed for the disposables used with the vacuum unit. Performance of the system shows substantial equivalence to the predicates.



JUN 23 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Frank Fucile, JD, RAC
Director, Global Regulatory Affairs
ACMI Corporation
Global Headquarters
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K030935
Trade/Device Name: Berkeley® VC-10 Vacurette
Curette System
Regulation Number: 21 CFR 884.5070
Regulation Name: Vacuum abortion system
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial suction curette
and accessories
Regulatory Class: II
Product Code: 85 HHI and HHK
Dated: March 21, 2003
Received: March 25, 2003

Dear Mr. Fucile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

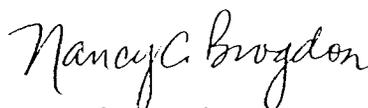
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JUN 23 2003

V. Statement of Intended Use.

510(k) Number (if Known): K030935

Device Name:

Berkeley® VC-10 Vacuum Curettage System

Indications For Use:

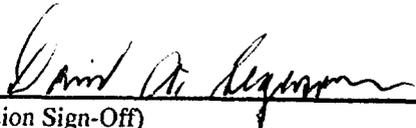
For rapid transcervical aspiration of the uterine cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR

Over-The-Counter Use
(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K030935